REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1-7 and 9-15 remain in this application.

II. Specification

The Examiner has objected to the disclosure because it contains an embedded hyperlink. Applicants have deleted the embedded hyperlink by this amendment. Accordingly, the objection should be withdrawn.

III. Claim Rejections – 35 U.S.C. § 103

The Examiner has rejected claims 1-7 and 9-15 as allegedly unpatentable over U.S. Patent No. 5,466,446 ("Stiefel et al.") or U.S. 4,545,977 ("Gaull") in view of U.S. Patent No. 5,304,112 ("Mrklas et al."). Applicants respectfully traverse this rejection.

Applicants claimed invention relates to a method for reducing the number and severity of acne lesions on the skin of a mammal. The method comprises the step of administering a sensory regimen in an amount effective to downregulate the activity of the HPA axis of said mammal in combination with the administration of an anti-acne composition comprising an effective amount of an anti-acne agent. The sensory regimen comprises at least two stimuli selected from the group consisting of auditory stimuli, visual stimuli, tactile stimuli, gustatory stimuli and olfactory stimuli, and combinations thereof and is effective to downregulate the activity of the HPA axis and wherein said activity of the HPA axis is downregulated by at least one of the following methods: (1) reducing the amount of total daily adrenocortical hormone; (2) reducing adrenocortical hormone at any time point in the period from about 4 to about 8 hours following morning waking; (3) reducing the total daily adrenocortical hormone minus the integrative measure of morning peak adrenocortical hormone.

Indeed, Applicants have shown that the addition of a sensory regimen comprising at least two stimuli in combination with an anti-acne composition demonstrated significant reduction in the number of inflammatory lesions when compared to the administration of an anti-acne

composition alone. See Example 2. Further, Applicants have demonstrated in Example 3, Tables 6-9, that the sensory regimen by itself showed broad emotional and well-being benefits. The use of a sensory regimen in combination with an anti-acne composition to reduce the number and severity of acne lesions on the skin of a mammal is neither taught nor suggested by the prior art relied upon by the Examiner.

The Examiner relies upon Stiefel and Gaull as teaching anti-acne compositions. Recognizing that neither Stiefel nor Gaull teach or suggest the administration of a sensory regimen in an amount effective to down regulate the activity of the HPA axis, the Examiner relies upon Mrklas et al.

Mrklas et al. relates to an integrated stress reduction system which comprises several components. There is no teaching or suggestion in Mrklas et al. that the stress reduction system could be used in combination with an anti-acne composition to reduce the number and severity of acne lesions on the skin of a mammal. The Examiner argues that because acne causes stress "the administration of the anti-acne composition of Stiefel or Gaull together with the system of Mrklas et al. would have been obvious to one of ordinary skill in the art to help reduce the acne lesions and decrease the stress levels caused by it." Applicants respectfully disagree.

As discussed above, Applicants invention relates to the administration of a sensory regimen in combination with an anti-acne composition to reduce the number and severity of acne lesions on the skin of a mammal. As demonstrated by Example 2, the addition of a sensory regimen comprising at least two stimuli in combination with an anti-acne composition demonstrated significant reduction in the number of inflammatory lesions when compared to the administration of an anti-acne composition alone. There is nothing in the teachings or Mrklas et al. that would provide one of ordinary skill in the art with the expectation that the stress reduction system of Mrklas et al. could be used to reduce the number and severity of acne lesions on the skin of a mammal.

Furthermore, there is no teaching or suggestion in Mrklas et al. of a sensory regimen that is effective to downregulate the activity of the HPA axis by at least one of the following methods: (1) reducing the amount of total daily adrenocortical hormone; (2) reducing

adrenocortical hormone at any time point in the period from about 4 to about 8 hours following morning waking; (3) reducing the total daily adrenocortical hormone minus the integrative measure of morning peak adrenocortical hormone. As discussed in parent application Serial No. 10/017,180 (the disclosure of which has been incorporated by reference), the term "total daily adrenocortical hormone" refers to the total amount of adrenocortical hormone secreted throughout the wakeful period in a 24 hour period typically divided into a period of wakefulness and a period of sleepfulness.

Further, the term "adrenocortical hormone in a mammal in the period from about 4 to about 8 hours following morning waking" refers to the amount of adrenocortical hormone secreted at any point in the 4 to 8 hours following morning waking, in any increments of time, for example minutes and hours.

Finally, the term "total daily adrenocortical hormone minus the integrative measure of morning peak adrenocortical hormone" refers to the total amount of adrenocortical hormone secreted throughout the wakeful period in a 24 hour period typically divided into a period of wakefulness and a period of sleepfulness, as defined above, having subtracted the area under the morning peak.

There is no teaching or suggestion in any of the references relied upon by the Examiner of a method for downregulating the activity of the HPA axis by at least one of the following methods: (1) reducing the amount of total daily adrenocortical hormone; (2) reducing adrenocortical hormone at any time point in the period from about 4 to about 8 hours following morning waking; (3) reducing the total daily adrenocortical hormone minus the integrative measure of morning peak adrenocortical hormone.

For all these reasons, Applicants respectfully submit that the rejection of claims 1-7 and 9-16 should be withdrawn.

IV. Conclusion

Applicants believe that the foregoing presents a full and complete response to the outstanding Office Action. An early and favorable response to this Amendment is earnestly solicited. If the Examiner feels that a discussion with Applicants' representative would be helpful in resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP-571/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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